IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Bial - Portela & C[a]., S.A.

Trademark: APTIOM

Class: 16

Serial No.: 86/277037

Ref.: 508.11(US16)

REQUEST FOR RECONSIDERATION

Applicant hereby requests reconsideration of the decision of the Examining Attorney in the Office Action dated May 4, 2015. A Notice of Appeal to the Trademark Trial and Appeal Board is being filed simultaneously herewith.

Introduction

The Examining Attorney has made final the refusal to register the applied-for mark, APTIOM, under Section 2(d) of the Trademark Act (15 U.S.C. Section 1062(d)), on the stated basis that it is likely to be confused with U.S. Reg. No. 3,727,530, which issued on December 22, 2009.

Applicant Bial-Portela & Ca ("Bial") respectfully disagrees with the refusal to register for the reasons indicated in its previously-filed Response to Office Action (dated February 27, 2015), the entire contents of which, including exhibits thereto, is incorporated herein by reference.

The owner of the cited registration, Sumitomo Dainippon Pharma Co., Ltd. ("SDP") has an indirect, wholly-owned subsidiary known as Sunovion Pharmaceuticals Inc. ("Sunovion"). *See* Exhibit A attached to the previous response, which consists of an excerpt from SDP's corporate information showing the status of Sunovion. Since Sunovion is a wholly-owned subsidiary of SDP, Sunovion's activities inure to the benefit of SDP, and for the purposes of the evaluation under Section 2(d), these two related companies are properly considered as one.

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Trademarks, P.O. Box 1451, Alexandria, Virginia 22313-1451 on the date shown below:

DIANE B. MELNICK

(Typed/Printed Name of Person Signing Certificate)

Diane B Melnick — NOV 4, 2015

(Signature) (Date)

In addition to the evidence that is already of record in this application , Applicant hereby submits the following exhibits for consideration by the Examining Attorney:

> **Exhibit I:** Photographs showing the packaging for the product associated with the APTIOM trademark. Please note that the products bear the trademark APTIOM, but also bear a design mark which is owned by Bial. That design mark is used to identify the product on which the trademark APTIOM is used, and also identifies Bial as a source of that APTIOM product;
>
> **Exhibit J:** A copy of the Certificates of Registration, U.S. Reg. Nos. 4,557,803 and 4,557,804, for the aforementioned design;
>
> **Exhibit K:** Press releases, consistent with those already of record, identifying the mark APTIOM as used under license from Bial and confirming the corporate relationship between SDP and Sunovion; and
>
> **Exhibit L:** Promotional material for the APTIOM product, showing the trade names of both Bial and Sunovion, adjacent to one another and comparable in size, and also confirming the corporate relationship noted above. Consistent with the arguments presented herein (see p. 3, infra), Exhibit L constitutes direct evidence of the cooperation between SDP (through its subsidiary Sunovion) and Bial and shows that the mark APTIOM is used on products which emanate from that cooperation. There is a single product on which the APTIOM trademark will be used, and that product was developed by Bial, licensed to Sunovion by Bial, and marketed by Sunovion in the course of the parties' business relationship, with SDP's full knowledge.

Contractual Relationship Between the Parties

Sunovion and Bial have an active contractual relationship which governs the ownership and use of the trademark APTIOM on the products identified in the application which specifically provides for a license of the trademark APTIOM from Bial to Sunovion, allowing the latter to use the trademark APTIOM with control of the trademark retained by Bial. *See* Exhibits C and E attached to the previously-filed Response to Office Action, consisting of press releases identifying and confirming the nature of the parties' relationship.

The Examining Attorney has noted that the "overriding concern is not only to prevent buyer confusion as to the source of the goods, but to protect the registrant from adverse commercial impact due to use of a similar mark by a newcomer." (*See* Final Office Action, p. 2). The evidence of record, including exhibits submitted herewith, is uncontroverted and clearly shows that **both** SDP and Sunovion identify the trademark APTIOM as being used "under license from Bial." This reflects the contractual relationship among the parties and their understanding of their respective rights in the trademark. The registrant will experience no

negative commercial impact whatsoever, as the parties have not only addressed this issue in an agreement, but have acted – and are acting – in a manner consistent with that agreement.

The evidence of record – all of which is uncontroverted – demonstrates that SDP (through its subsidiary Sunovion) and Bial each have specific responsibilities with respect to the process of bringing the APTIOM product into the marketplace. The responsibilities (and rights) with respect to the trademark APTIOM itself are Bial's. This contention is clearly supported by the evidence that is of record, which consistently identifies the trademark APTIOM as used **under license from Bial**. The fact of a license from Bial presupposes the fact that Bial has substantive rights in the trademark APTIOM that it is able to license to Sunovion.

The statement that the APTIOM product is used "under license by Bial" (*see* Exhibits I, K, and L and exhibits previously submitted) is a specific articulation of Bial's rights in the trademark and its inclusion on the product labels and related materials constitutes an explicit assent by SDP and Sunovion to those rights. Based on the plain language of the aforementioned statement, it is reasonable to construe it as an acknowledgement by SDP of Bial's control over the mark APTIOM, including its right to license same. There is no other basis for the mark to be licensed by Bial to Sunovion. In acknowledging Bial's rights in the APTIOM trademark and the licensing certain of those rights in connection with the marketing of the products associated with the APTIOM trademark, SDP implicitly must agree: 1) that the trademark as used by the parties in furtherance of their agreement is controlled by Bial; and 2) that Bial is entitled to registration of the trademark.

This position is also supported by Exhibits I and J attached hereto. The use of Bial's registered Design mark on a product which is also identified by the trademark APTIOM is a clear acknowledgement by SDP of the relationship between the parties. It is also direct evidence that Bial is one of the sources of the APTIOM pharmaceutical product. There is no other plausible rationale for Bial to allow such use of its design mark on the APTIOM product.

The statement shown in the evidence of record (that is, that the APTIOM product is sold "under license by Bial") is the public manifestation of Sunovion and SDP's agreement to the use of the APTIOM trademark under license from Bial, which permits its use by SDP through its subsidiary Sunovion. That statement is an express acknowledgment of the parties' cooperation in connection with the development and marketing of the products on which the trademark APTIOM is used. That cooperation means that each party has a role in bringing the APTIOM product to market and works with the other to do so. This is a textbook example of how parties can prevent a likelihood of consumer confusion, by assuming specific responsibilities with respect to a trademark and its associated goods, cooperating in the use of the mark on the goods, and informing the public of that cooperation.

In the previously-filed Response to Office Action, Bial submitted copies of the FDA-approved label for the APTIOM product (*see* Exhibit G, attached to the previous Response). The product labels also include a designation to indicate that the APTIOM product is "under license by Bial." See also Exhibit I, attached hereto, which is a current label for the blister pack of the 400 mg dose of the APTIOM pharmaceutical. It bears the same language as shown in Exhibit G attached to the previously-filed Response to Office Action. Moreover, Exhibit I shows

that the trademark/trade name BIAL (owned by Bial – see U.S. Reg. No. 4,490,162, as shown in the certificate of registration attached hereto as Exhibit M) is used immediately adjacent to the trademark/trade name SUNOVION (owned by SDP – see U.S. Reg. No. 4,096,601, as shown in the certificate of registration attached hereto as Exhibit N) in a comparable size. This is further direct evidence of the parties' cooperation which will prevent any likelihood of confusion.

Lack of Consumer Confusion

In addition, the present application was filed on the basis of use of the mark in commerce since April 7, 2014. *See* specimen of use of record in this application. The mark has been used in commerce for well over a year as a result of the parties' agreement and subsequent cooperation. Moreover, the marketing strategy for the APTIOM product has been developed well before that date, with the full knowledge of all three parties, SDP, Sunovion, and Bial.

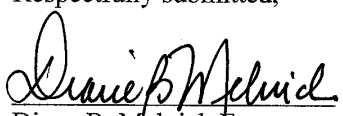
Conclusion

The Examining Attorney has noted two concerns upon which the refusal to register is based: 1) consumer confusion; and 2) protecting the registrant from a negative commercial impact from a later-filed application. In terms of the first noted concern, that is, consumer confusion, the uncontroverted evidence and arguments presented in this matter demonstrate that confusion is unlikely. Consumers will know, from the product materials and packaging, the specific sources of the APTIOM product. SDP – through its subsidiary Sunovion -- and Bial have taken specific steps to ensure that there is no likelihood of consumer confusion by clearly identifying themselves on the product materials and packaging. This pattern of source identification is consistent across all of the materials that are of record in this matter. On the second issue, that is, potentially negative commercial impact, it is clear from SDP/Sunovion's placement of its trade name/trademark alongside that of Bial and the inclusion of the language "under license from BIAL" that the registrant itself recognizes Bial's rights in the mark and is not concerned about any negative commercial impact.

For the reasons noted above, the refusal to register is properly withdrawn, and the application forwarded for publication in due course. If further information or clarification is required, please do not hesitate to contact the undersigned.

Respectfully submitted,

Dated: NOV. 4, 2015



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Attorneys for Applicant
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New York, NY 10013
212-226-5054 (phone)
212-226-5085 (fax)

EXHIBIT I

ONCE DAILY
Aptiom®
(eslicarbazepine acetate) Tablets
400 mg

Open wallet and push tablet through wallet from the inside.

ONCE DAILY
Aptiom®
(eslicarbazepine acetate) Tablets
400 mg

Usual dosage: Take prescribed dose by mouth once daily or as directed. See package insert for dosage information.

Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F).

Aptiom does not require controlled substance storage or protocols.

Keep out of reach of children. Package not child resistant.

Manufactured for
Sunovion Pharmaceuticals Inc.
Marlborough, MA 01752 USA

Made in Canada

For more **Aptiom** information, call 1-888-394-7377.
www.aptiom.com

901674R00

SUNOVION

Under license from Biad

400 mg
per tablet

NDC 63402-204-07

ONCE DAILY
Aptiom®
(eslicarbazepine acetate) Tablets
400 mg

Rx Only

ATTENTION DISPENSER: Dispense the enclosed Medication Guide to each patient.

This package contains 7 tablets.

Professional Sample
Not for Sale or Reimbursement

What is Aptiom?

For Medication Guide,
look inside the pocket below.

ONCE DAILY
Aptiom®
(eslicarbazepine acetate) Tablets

www.aptiom.com

Learn More

For more information on Aptiom,
look inside the pocket below.

INSTRUCTIONS FOR PATIENT:

ONCE DAILY
Aptiom®
(eslicarbazepine acetate) Tablets
400 mg

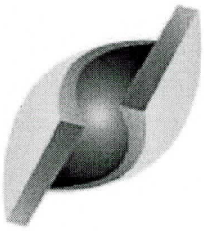
Each tablet contains:
eslicarbazepine acetate 400 mg.

Take prescribed dose by mouth once daily or as directed.

400 mg
per tablet

EXHIBIT J

United States of America
United States Patent and Trademark Office



Reg. No. 4,557,804

Registered July 1, 2014

Int. Cls.: 5, 16 and 44

TRADEMARK

SERVICE MARK

PRINCIPAL REGISTER

BIAL - PORTELA & Cª, S.A. (PORTUGAL CORPORATION)
A AV. DA SIDERURGIA NACIONAL
S. MAMEDE DO CORONADO
-, PORTUGAL 4745457

FOR: PHARMACEUTICAL PRODUCTS AND PREPARATIONS, NAMELY, PRODUCTS FOR THE TREATMENT OF EPILEPSY, NEUROPATHIC PAIN, AND AFFECTIVE DISORDERS; ANTI-EPILEPTIC DRUGS; PHARMACEUTICAL PRODUCTS AND PREPARATIONS FOR THE TREATMENT OF DISEASES AND DISORDERS OF THE CENTRAL AND PERIPHERAL NERVOUS SYSTEM, IN CLASS 5 (U.S. CLS. 6, 18, 44, 46, 51 AND 52).

FOR: PRINTED MATERIALS, NAMELY, NEWSLETTERS, PERIODICALS, BOOKLETS, BROCHURES, AND PAMPHLETS IN THE FIELDS OF CENTRAL AND PERIPHERAL NERVOUS SYSTEM DISEASE TREATMENT AND PREVENTION; STATIONERY; STICKERS; AND WRITING INSTRUMENTS, NAMELY, PENS, PENCILS, CRAYONS, AND MARKERS, IN CLASS 16 (U.S. CLS. 2, 5, 22, 23, 29, 37, 38 AND 50).

FOR: PROVIDING MEDICAL INFORMATION RELATING TO ONGOING RESEARCH PROGRAMS AND STUDIES IN THE FIELDS OF CENTRAL AND PERIPHERAL NERVOUS SYSTEM DISEASE TREATMENT AND PREVENTION; PROVIDING MEDICAL INFORMATION IN THE FIELDS OF CENTRAL AND PERIPHERAL NERVOUS SYSTEM CONDITIONS VIA THE INTERNET, IN CLASS 44 (U.S. CLS. 100 AND 101).

OWNER OF PORTUGAL REG. NO. 517918, DATED 10-18-2013, EXPIRES 10-18-2023.

THE MARK CONSISTS OF A CURVED, GEOMETRIC BAR THAT FORMS THE LETTER "S" AT THE CENTER.

SER. NO. 77-899,274, FILED 12-22-2009.

JASON TURNER, EXAMINING ATTORNEY

UNITED STATES PATENT AND TRADEMARK OFFICE · DEPARTMENT OF COMMERCE

Michelle K. Lee

Deputy Director of the United States Patent and Trademark Office

REQUIREMENTS TO MAINTAIN YOUR FEDERAL TRADEMARK REGISTRATION

WARNING: YOUR REGISTRATION WILL BE CANCELLED IF YOU DO NOT FILE THE DOCUMENTS BELOW DURING THE SPECIFIED TIME PERIODS.

Requirements in the First Ten Years*
What and When to File:

First Filing Deadline: You must file a Declaration of Use (or Excusable Nonuse) between the 5th and 6th years after the registration date. *See* 15 U.S.C. §§1058, 1141k. If the declaration is accepted, the registration will continue in force for the remainder of the ten-year period, calculated from the registration date, unless cancelled by an order of the Commissioner for Trademarks or a federal court.

Second Filing Deadline: You must file a Declaration of Use (or Excusable Nonuse) **and** an Application for Renewal between the 9th and 10th years after the registration date.* *See* 15 U.S.C. §1059.

Requirements in Successive Ten-Year Periods*
What and When to File:

You must file a Declaration of Use (or Excusable Nonuse) **and** an Application for Renewal between every 9th and 10th-year period, calculated from the registration date.*

Grace Period Filings*

The above documents will be accepted as timely if filed within six months after the deadlines listed above with the payment of an additional fee.

The United States Patent and Trademark Office (USPTO) will NOT send you any future notice or reminder of these filing requirements.

***ATTENTION MADRID PROTOCOL REGISTRANTS:** The holder of an international registration with an extension of protection to the United States under the Madrid Protocol must timely file the Declarations of Use (or Excusable Nonuse) referenced above directly with the USPTO. The time periods for filing are based on the U.S. registration date (not the international registration date). The deadlines and grace periods for the Declarations of Use (or Excusable Nonuse) are identical to those for nationally issued registrations. *See* 15 U.S.C. §§1058, 1141k. However, owners of international registrations do not file renewal applications at the USPTO. Instead, the holder must file a renewal of the underlying international registration at the International Bureau of the World Intellectual Property Organization, under Article 7 of the Madrid Protocol, before the expiration of each ten-year term of protection, calculated from the date of the international registration. *See* 15 U.S.C. §1141j. For more information and renewal forms for the international registration, see http://www.wipo.int/madrid/en/.

NOTE: Fees and requirements for maintaining registrations are subject to change. Please check the USPTO website for further information. With the exception of renewal applications for registered extensions of protection, you can file the registration maintenance documents referenced above online at http://www.uspto.gov.

United States of America
United States Patent and Trademark Office

Reg. No. 4,557,803

Registered July 1, 2014

Int. Cl.: 5

TRADEMARK

PRINCIPAL REGISTER

BIAL - PORTELA & Cª, S.A. (PORTUGAL CORPORATION)
A AV. DA SIDERURGIA NACIONAL
S. MAMEDE DO CORONADO
-, PORTUGAL 4745457

FOR: PHARMACEUTICAL PRODUCTS AND PREPARATIONS, NAMELY, PRODUCTS FOR THE TREATMENT OF EPILEPSY, NEUROPATHIC PAIN, AND AFFECTIVE DISORDERS; ANTI-EPILEPTIC DRUGS; PHARMACEUTICAL PRODUCTS AND PREPARATIONS FOR THE TREATMENT OF DISEASES AND DISORDERS OF THE CENTRAL AND PERIPHERAL NERVOUS SYSTEM, IN CLASS 5 (U.S. CLS. 6, 18, 44, 46, 51 AND 52).

OWNER OF PORTUGAL REG. NO. 517917, DATED 10-18-2013, EXPIRES 10-18-2023.

THE COLOR(S) BLUE, PURPLE AND WHITE IS/ARE CLAIMED AS A FEATURE OF THE MARK.

THE MARK CONSISTS OF A CURVED GEOMETRIC BAR THAT APPEARS BLUE ON THE OUTSIDE AND PURPLE AND WHITE AT THE CENTER THAT FORM AN "S".

SER. NO. 77-899,267, FILED 12-22-2009.

JASON TURNER, EXAMINING ATTORNEY

Michelle K. Lee

Deputy Director of the United States Patent and Trademark Office

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NOTE: Fees and requirements for maintaining registrations are subject to change. Please check the USPTO website for further information. With the exception of renewal applications for registered extensions of protection, you can file the registration maintenance documents referenced above online at http://www.uspto.gov.

EXHIBIT K

Sunovion Pharmaceuticals Inc.
84 Waterford Drive, Marlborough, MA 01752-7010
Tel 508-481-6700

SUNOVION

SEE PAGE 2

News Release

Contact: Patricia Moriarty
Senior Director, Corporate Communications
Sunovion Pharmaceuticals Inc.
(508) 787-4279
patricia.moriarty@sunovion.com

Sunovion Pharmaceuticals Inc. Announces FDA Approval of Aptiom® (eslicarbazepine acetate) as Once-Daily Adjunctive Treatment of Partial-Onset Seizures

Marlborough, Mass., November 8, 2013 – Sunovion Pharmaceuticals Inc. (Sunovion) today announced that the U.S. Food and Drug Administration (FDA) approved Aptiom® (eslicarbazepine acetate), an antiepileptic drug (AED), for use as adjunctive treatment of partial-onset seizures. Epilepsy is one of the most common neurological disorders and, according to the Centers for Disease Control and Prevention, affects nearly 2.2 million people in the United States (U.S.).[i] Partial-onset seizures are the most prevalent seizure type, accounting for 60% of new epilepsy diagnoses.[ii]

"Patients with partial-onset epilepsy often require adjunctive treatment to achieve better seizure control," said Dr. Joseph Sirven, M.D., Chair of Neurology at Mayo Clinic in Arizona and Chair of the Epilepsy Foundation's Professional Advisory Board. "APTIOM is an important new treatment option with a well-established safety profile for healthcare providers and people living with epilepsy."

The FDA has determined that APTIOM will not be classified as a controlled substance. Sunovion expects APTIOM to be available in U.S. pharmacies in the second quarter (April – June) of 2014.

The approval of APTIOM is based on three large Phase 3 randomized, double-blind, placebo-controlled, safety and efficacy trials (Studies BIA 2093-301, BIA-2093-302 and BIA-2093-304), which included more than 1,400 people living with partial-onset seizures inadequately controlled by one to three concomitant AEDs (including carbamazepine, lamotrigine, valproic acid and levetiracetam). In these global studies, which were jointly performed with BIAL-Portela & C[a], S.A. (BIAL), treatment with APTIOM demonstrated statistically significant reductions in standardized seizure frequency versus placebo, and significantly more APTIOM treated patients experienced seizure frequency reduction of 50% or more from baseline (41% compared to 22% for placebo-treated patients).

The most common side effects in patients taking APTIOM include dizziness, somnolence, nausea, headache, diplopia, vomiting, fatigue, vertigo, ataxia, blurred vision and tremor. The rate of discontinuation as a result of any adverse event was 14% for the 800 mg dose, 25% for the 1,200 mg dose and 7% in subjects randomized to placebo.

"APTIOM will offer people with partial-onset seizures sustained seizure reduction in a once-daily, immediate-release formulation," said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer at Sunovion. "The approval today significantly expands the treatment options Sunovion offers to

patients with complex neurological disorders, and it marks the second FDA approval action this year for the Company's central nervous system products."

About Partial-Onset Seizures

Epilepsy is characterized by abnormal firing of impulses from nerve cells in the brain.[iii] In partial-onset seizures, these bursts of electrical activity are initially focused in specific areas of the brain, but may become more widespread, with symptoms varying according to the affected areas.[iv,v] The unpredictable nature of seizures can have a significant impact on those with epilepsy, affecting a number of areas of daily living, including education, employment, driving and recreation. Reducing the frequency of seizures can greatly lessen the burden of epilepsy.[i] With approximately 30% of people living with epilepsy still unable to control seizures, there continues to be a need for new therapies.[vi]

About APTIOM

APTIOM, a voltage-gated sodium channel inhibitor, is a prescription medicine approved for use as adjunctive treatment of partial-onset seizures. Treatment with APTIOM should be initiated at 400 mg once daily. After one week, dosage may be increased to the recommended maintenance dosage of 800 mg once daily. Some patients may benefit from the maximum recommended maintenance dosage of 1,200 mg once daily, although this dosage is associated with an increase in adverse reactions. The maximum dose of 1,200 mg daily should only be initiated after the patient has tolerated 800 mg daily for at least a week. For some patients, treatment may be initiated at 800 mg once daily if the need for additional seizure reduction outweighs an increased risk of adverse reactions during initiation.

The initial research and development of eslicarbazepine acetate was performed by BIAL, a privately held Portuguese research-based pharmaceutical company. Subsequently, Sunovion acquired the rights under an exclusive license to further develop and commercialize eslicarbazepine acetate in the U.S. and Canadian markets from BIAL. In February 2009, Eisai Europe Limited, a European subsidiary of Eisai Co., Ltd. (Eisai), entered into a license and co-promotion agreement with BIAL, which gave the rights to Eisai to sell eslicarbazepine acetate under the trade name Zebinix® in Europe. Zebinix was approved by the European Commission on April 21, 2009 as adjunctive therapy in adult patients with partial-onset seizures with or without secondary generalization and is currently marketed in Europe under the agreement.

Please see Important Safety Information below.

Sunovion Support™, the Sunovion patient assistance program, may help eligible patients receive APTIOM at no charge to the patient when it becomes available. Following the launch of APTIOM, more information on this program, including eligibility criteria, may be found at www.SunovionSupport.com.

Indication

APTIOM (eslicarbazepine acetate) is a prescription medicine used with other medicines to treat partial-onset seizures.

Important Safety Information

Do not take APTIOM if you are allergic to eslicarbazepine acetate, any of the other ingredients in APTIOM or oxcarbazepine.

APTIOM may cause suicidal thoughts or actions, depression or mood problems. Call your doctor right away if you experience these or any other effects or reactions.

APTIOM may cause serious skin rash or other serious allergic reactions, which may affect organs or other parts of your body like the liver or blood cells. Some symptoms may include: swelling of the face, eyes, lips or tongue, trouble swallowing or breathing, yellowing of the skin or eyes or severe fatigue or weakness.

APTIOM may cause the level of sodium in your blood to be low. Symptoms may include nausea, tiredness, lack of energy, irritability, confusion, muscle weakness or muscle spasms, or more frequent or more severe seizures.

APTIOM may cause problems that can affect your nervous system including dizziness, sleepiness, vision problems and difficulties with coordination and balance.

APTIOM may slow your thinking or motor skills. Do not drive or operate heavy machinery until you know how APTIOM affects you.

Do not stop taking APTIOM without first talking to your healthcare provider. Stopping APTIOM suddenly can cause serious problems.

APTIOM may cause problems that can affect your liver. Symptoms of liver problems include yellowing of your skin or the whites of your eyes and nausea or vomiting.

The most common side effects in patients taking APTIOM include dizziness, sleepiness, nausea, headache, double vision, vomiting, feeling tired, problems with coordination, blurred vision and shakiness.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

About Sunovion Pharmaceuticals Inc. (Sunovion)

Sunovion is a leading pharmaceutical company dedicated to discovering, developing and commercializing therapeutic products that advance the science of medicine in the Psychiatry & Neurology and Respiratory disease areas and improve the lives of patients and their families. Sunovion's drug development program, together with its corporate development and licensing efforts, has yielded a portfolio of pharmaceutical products including Aptiom® (eslicarbazepine acetate), Latuda® (lurasidone HCl) tablets, Lunesta® (eszopiclone) tablets, Xopenex® (levalbuterol HCl) inhalation solution, Xopenex HFA® (levalbuterol tartrate) inhalation aerosol, Brovana® (arformoterol tartrate) inhalation solution, Omnaris® (ciclesonide) nasal spray, Zetonna® (ciclesonide) nasal aerosol and Alvesco® (ciclesonide) inhalation aerosol.

Sunovion, an indirect, wholly-owned U.S. subsidiary of Dainippon Sumitomo Pharma Co., Ltd., is headquartered in Marlborough, Mass. More information about Sunovion Pharmaceuticals Inc. is available at www.sunovion.com.

About Dainippon Sumitomo Pharma Co., Ltd. (DSP)

DSP is a top-ten listed pharmaceutical company in Japan with a diverse portfolio of pharmaceutical, animal health and food and specialty products. DSP aims to produce innovative pharmaceutical products in the Psychiatry & Neurology area and the Oncology area, which have been designated as the focus therapeutic areas. DSP is based on the merger in 2005 between Dainippon Pharmaceutical Co., Ltd., and Sumitomo Pharmaceuticals Co., Ltd. Today, DSP has more than 7,000 employees worldwide. Additional information about DSP is available through its corporate website at www.ds-pharma.com.

For a copy of this release, visit Sunovion's web site at www.sunovion.com

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[i] IOM (Institute of Medicine). 2012. Epilepsy across the spectrum: Promoting health and understanding. Washington, DC: The National Academies Press.
[ii] Hauser WA, Annegers JF, Kurland LT. Prevalence of Epilepsy in Rochester, Minnesota: 1940-1980. *Epilepsia*. 1991;32:429-445.
[iii] National Institutes of Health. "NINDS Epilepsy Information Page" Accessed 5 September 2013. <http://www.ninds.nih.gov/disorders/epilepsy/epilepsy.htm>
[iv] Epilepsy Foundation. "Partial Seizures." Accessed 5 September 2013. <"http://www.epilepsyfoundation.org/aboutepilepsy/seizures/partialseizures/index.cfm>
[v] Dartmouth Medical School. "Disorders of the Central Nervous System: A Primer (Chapter 22: Epilepsy)." Accessed 5 September 2013. <http://www.dartmouth.edu/~*dons*/part_3/chapter_22.html>
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SUNOVION

SEE PAGE 4

News Release

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Sunovion Pharmaceuticals Inc. Announces FDA Acceptance for Review of Supplemental New Drug Application for the Use of Aptiom® (eslicarbazepine acetate) as Monotherapy Treatment for Partial-Onset Seizures

Marlborough, Mass., January 7, 2015 – Sunovion Pharmaceuticals Inc. (Sunovion) announced today the U.S. Food and Drug Administration (FDA) has accepted for review a supplemental New Drug Application (sNDA) for the use of Aptiom® (eslicarbazepine acetate) as monotherapy treatment of partial-onset seizures. The sNDA was submitted to the FDA by Sunovion on October 29, 2014 and included data from two Phase 3 double-blind, historical-controlled, multi-center randomized trials involving patients with partial-onset seizures.

"APTIOM has been well-received for use as an adjunctive treatment in partial-onset seizures," said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer, Sunovion. "We are pleased with the FDA's acceptance of the filing for review and look forward to potential approval of APTIOM as monotherapy with once-daily dosing for patients with this complex neurological disorder."

The two trials (Studies 093-046 and 093-045) were designed identically to evaluate the safety and efficacy of APTIOM (1,600 mg/day or 1,200 mg/day) as monotherapy treatment for partial-onset seizures in patients 16 years of age or older whose seizures were not well-controlled by other antiepileptic drugs (AEDs). All patients in Study 093-045 were evaluated in North America. Study 093-046 included approximately 25 percent of patients from the United States and approximately 75 percent from four European countries. The primary endpoint for both studies was the proportion of patients with partial-onset seizures meeting pre-defined exit criteria (signifying worsening seizure control) 16 weeks post-titration of APTIOM, in comparison to historical controls.

APTIOM is approved for use as adjunctive treatment of partial-onset seizures. APTIOM was launched in the United States on April 7, 2014. APTIOM is not approved for use as monotherapy for partial-onset seizures.

About Partial-Onset Seizures

Epilepsy is characterized by abnormal firing of impulses from nerve cells in the brain.[i] In partial-onset seizures, these bursts of electrical activity are initially focused in specific areas of the brain, but may become more widespread, with symptoms varying according to the affected areas.[ii,iii] The unpredictable nature of seizures can have a significant impact on those with epilepsy, affecting a number of areas of daily living, including education, employment, driving and recreation. Reducing the frequency of seizures can greatly lessen the burden of epilepsy.[iv] With approximately one-third of people living with epilepsy still unable to control seizures, there continues to be a need for new therapies.[v]

About Aptiom® (eslicarbazepine acetate)
APTIOM, a voltage-gated sodium channel inhibitor, is a prescription medicine approved for use as adjunctive treatment of partial-onset seizures, and is available in four tablet strengths (200 mg, 400 mg, 600 mg, and 800 mg), which can be taken whole or crushed, with or without food. APTIOM is not classified as a controlled substance by the FDA.

The initial research and development of eslicarbazepine acetate was performed by BIAL-Portela & Ca, S.A. (BIAL), a privately held Portuguese research-based pharmaceutical company. Subsequently, Sunovion acquired the rights under an exclusive license to further develop and commercialize eslicarbazepine acetate in the United States and Canadian markets from BIAL. BIAL gained approved for eslicarbazepine acetate from the European Commission on April 21, 2009 as adjunctive therapy in adult patients with partial-onset seizures with or without secondary generalization. In Europe, the product is marketed under the trade name Zebinix®.

Please see Important Safety Information below.

INDICATION:
Aptiom® (eslicarbazepine acetate) is a prescription medicine used with other medicines to treat partial-onset seizures.

IMPORTANT SAFETY INFORMATION:
Do not take APTIOM if you are allergic to eslicarbazepine acetate, any of the other ingredients in APTIOM, or oxcarbazepine.

Suicidal behavior and ideation: APTIOM may cause suicidal thoughts or actions, depression, or mood problems. Call your doctor right away if you experience these or any other effects or reactions: thoughts about suicide or dying; attempting to commit suicide; new or worse depression, anxiety, or irritability; feeling agitated or restless; panic attacks; trouble sleeping (insomnia); acting aggressive; being angry or violent; acting on dangerous impulses; an extreme increase in activity and talking (mania); or other unusual changes in behavior or mood.

Allergic reactions: APTIOM may cause serious skin rash or other serious allergic reactions that may affect organs or other parts of your body like the liver or blood cells. You may or may not have a rash with these types of reactions. Call your doctor right away if you experience any of the following symptoms: swelling of the face, eyes, lips, or tongue; trouble swallowing or breathing; hives; fever, swollen glands, or sore throat that do not go away or come and go; painful sores in the mouth or around your eyes; yellowing of the skin or eyes; unusual bruising or bleeding; severe fatigue or weakness; severe muscle pain; or frequent infections or infections that do not go away.

Low salt (sodium) levels in the blood: APTIOM may cause the level of sodium in your blood to be low. Symptoms may include nausea, tiredness, lack of energy, irritability, confusion, muscle weakness or muscle spasms, or more frequent or more severe seizures.

Nervous system problems: APTIOM may cause problems that can affect your nervous system, including dizziness, sleepiness, vision problems, trouble concentrating, and difficulties with coordination and balance. APTIOM may slow your thinking or motor skills. Do not drive or operate heavy machinery until you know how APTIOM affects you.

Liver problems: APTIOM may cause problems that can affect your liver. Symptoms of liver problems include yellowing of your skin or the whites of your eyes, nausea or vomiting, loss of appetite, stomach pain, or dark urine.

Most common adverse reactions: The most common side effects in patients taking APTIOM include dizziness, sleepiness, nausea, headache, double vision, vomiting, feeling tired, problems with coordination, blurred vision, and shakiness.

Drug interactions: Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking APTIOM with certain other medicines may cause side effects or affect how well they work. **Do not start or stop other medicines without talking to your healthcare provider.** Especially tell your healthcare provider if you take oxcarbazepine, carbamazepine, phenobarbital, phenytoin, primidone, clobazam, omeprazole, simvastatin, rosuvastatin, or birth control medicine.

Discontinuation: Do not stop taking APTIOM without first talking to your healthcare provider. Stopping APTIOM suddenly can cause serious problems.

Pregnancy and lactation: APTIOM may cause your birth control medicine to be less effective. Talk to your healthcare provider about the best birth control method to use. APTIOM may harm your unborn baby. APTIOM passes into breast milk. Tell your healthcare provider if you are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed. You and your healthcare provider will decide if you should take APTIOM. If you become pregnant while taking APTIOM, talk to your healthcare provider about registering with the North American Antiepileptic Drug (NAAED) Pregnancy Registry. The purpose of this registry is to collect information about the safety of antiepileptic medicine during pregnancy. You can enroll in this registry by calling 1-888-233-2334.

Get medical help right away if you have any of the symptoms listed above.
You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For more information, please see the APTIOM Medication Guide and Full Prescribing Information at www.APTIOM.com.

About Sunovion Pharmaceuticals Inc. (Sunovion)

Sunovion is a leading pharmaceutical company dedicated to discovering, developing and commercializing therapeutic products that advance the science of medicine in the Psychiatry, Neurology and Respiratory disease areas to improve the lives of patients and their families.

Sunovion, an indirect, wholly owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd., is headquartered in Marlborough, Mass. More information about Sunovion Pharmaceuticals Inc. is available at www.sunovion.com.

About Sumitomo Dainippon Pharma Co., Ltd.
Sumitomo Dainippon Pharma is a top-ten listed pharmaceutical company in Japan. Sumitomo Dainippon Pharma aims to produce innovative pharmaceutical products in the Psychiatry & Neurology area and the Oncology area, which have been designated as the focus therapeutic areas. Sumitomo Dainippon Pharma is based on the merger in 2005 between Dainippon Pharmaceutical Co., Ltd., and Sumitomo Pharmaceuticals Co., Ltd. Today, Sumitomo Dainippon Pharma has about 7,000 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at www.ds-pharma.com

APTIOM is used under license from BIAL.

Sunovion Pharmaceuticals Inc. is a U.S. subsidiary of Sumitomo Dainippon Pharma Co., Ltd.

For a copy of this release, visit Sunovion's web site at www.sunovion.com

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[iv] Institute of Medicine (IOM). 2012. "Epilepsy across the spectrum: Promoting health and understanding." Washington, DC: The National Academies Press.

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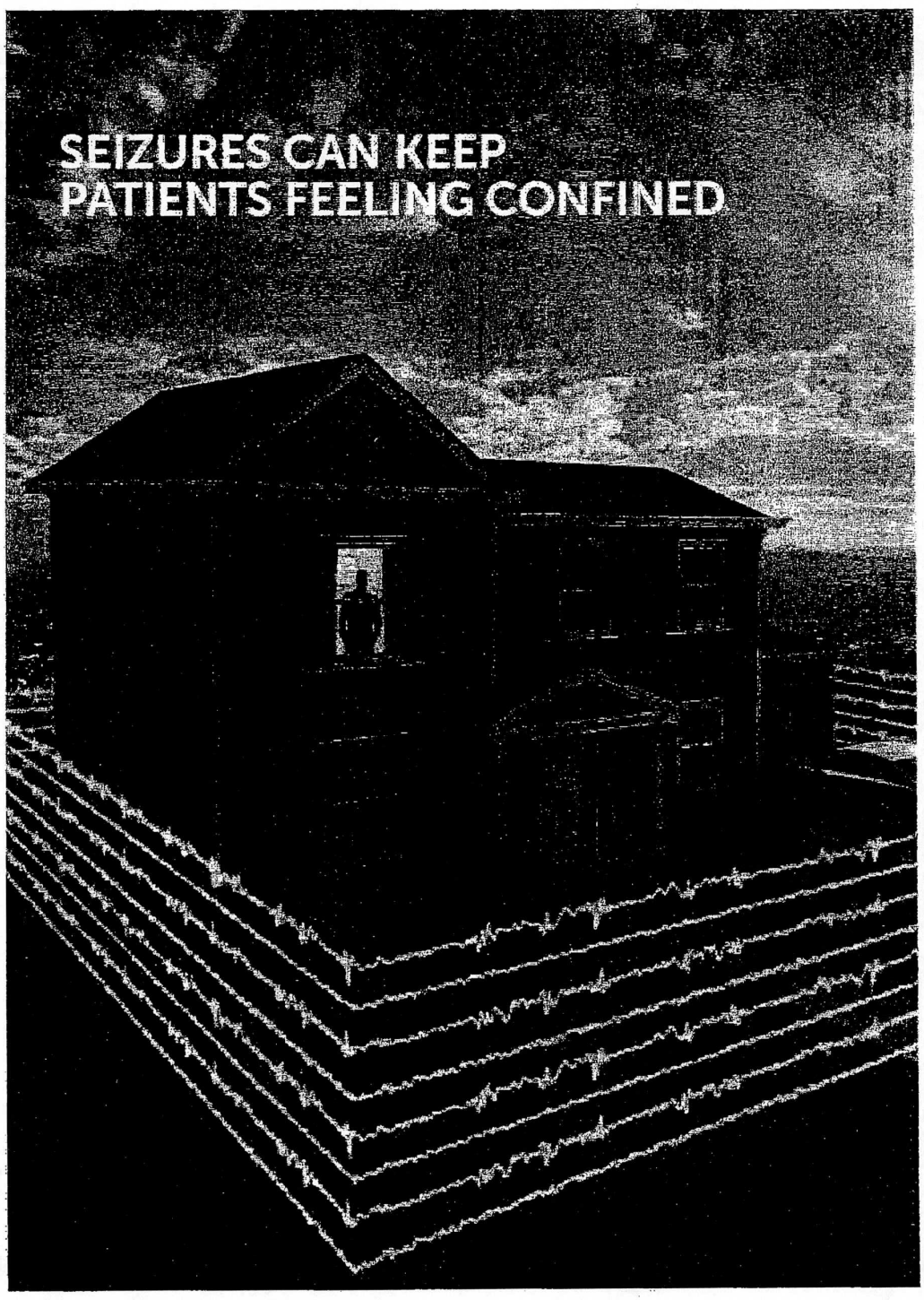
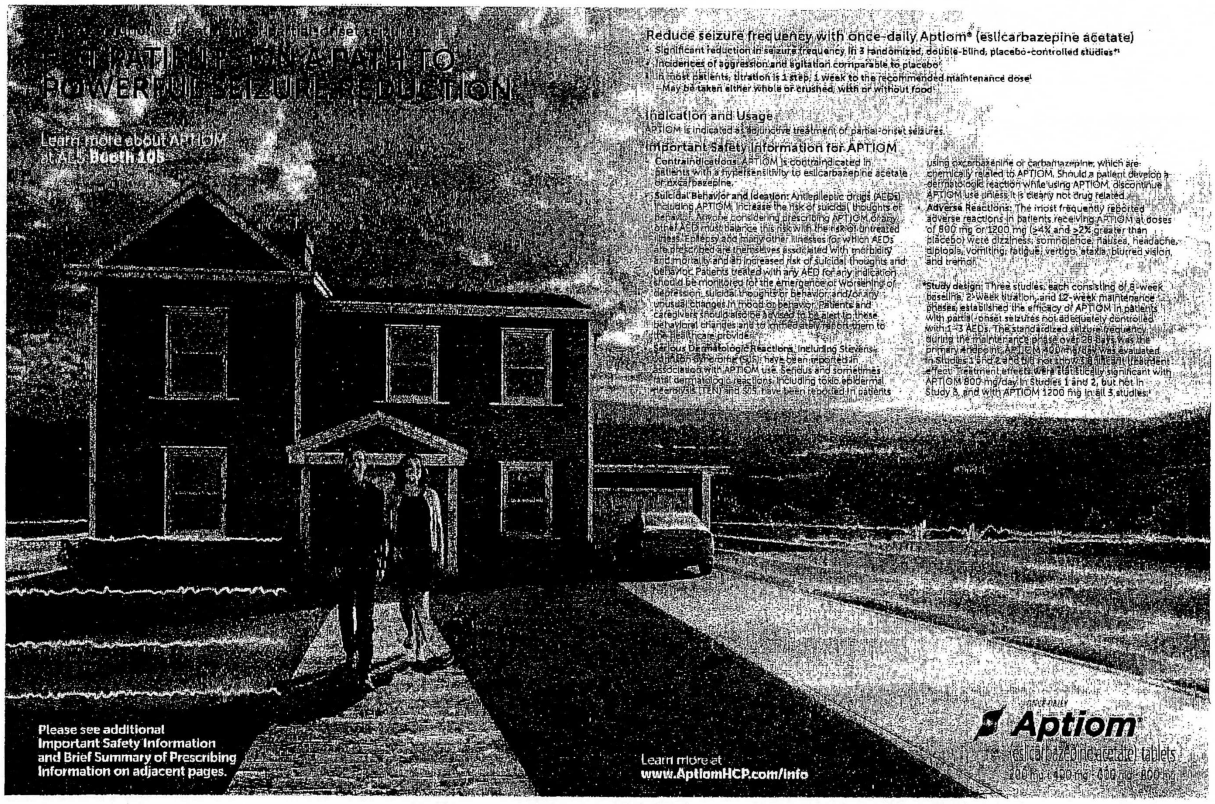
EXHIBIT L

SEE PAGES 3 AND 5





Reduce seizure frequency with once-daily Aptiom® (eslicarbazepine acetate)

- Significant reduction in seizure frequency in 3 randomized, double-blind, placebo-controlled studies[1]
- Incidences of aggression and agitation comparable to placebo[1]
- In most patients, titration is 1 step, 1 week to the recommended maintenance dose[1]
- May be taken either whole or crushed, with or without food[1]

Indication and Usage

APTIOM is indicated as adjunctive treatment of partial-onset seizures.

Important Safety Information for APTIOM

- Contraindications: APTIOM is contraindicated in patients with a hypersensitivity to eslicarbazepine acetate or oxcarbazepine.
- Suicidal Behavior and Ideation: Antiepileptic drugs (AEDs), including APTIOM, increase the risk of suicidal thoughts or behavior. Anyone considering prescribing APTIOM or any other AED must balance this risk with the risk of untreated illness. Epilepsy and many other illnesses for which AEDs are prescribed are themselves associated with morbidity and mortality and an increased risk of suicidal thoughts and behavior. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Patients and caregivers should be advised to be alert to these behavioral changes and to immediately report them to the healthcare provider.
- Serious Dermatologic Reactions: Serious and sometimes fatal dermatologic reactions, including toxic epidermal necrolysis (TEN) and SJS, have been reported in patients using oxcarbazepine or carbamazepine, which are chemically related to APTIOM. Should a patient develop a dermatologic reaction while using APTIOM, discontinue APTIOM use unless it is clearly not drug related.
- Adverse Reactions: The most frequently reported adverse reactions in patients receiving APTIOM at doses of 800 mg or 1200 mg (≥4% and ≥2% greater than placebo) were dizziness, somnolence, fatigue, headache, diplopia, vomiting, fatigue, vertigo, ataxia, blurred vision, and tremor.[1]

[1]Study design: Three studies, each consisting of a 6-week baseline, 2-week titration, and 12-week maintenance (3) phase, established the efficacy of APTIOM in patients with partial-onset seizures not adequately controlled with 1–3 AEDs. The standardized seizure frequency during the maintenance phase over the 28 days was the primary endpoint. APTIOM 400 mg/day was evaluated in Studies 1 and 2 and did not show a significant treatment effect. Treatment effects were statistically significant with APTIOM 800 mg/day in Studies 1 and 2, but not in Study 3, and with APTIOM 1200 mg in all 3 studies.[1]

(7)

For the adjunctive treatment of partial-onset seizures

PUT PATIENTS ON A PATH TO POWERFUL SEIZURE REDUCTION

Indication and Usage

Aptiom® (eslicarbazepine acetate) is indicated as adjunctive treatment of partial-onset seizures.

Important Safety Information for APTIOM

Contraindications: APTIOM is contraindicated in patients with a hypersensitivity to eslicarbazepine acetate or oxcarbazepine.

Suicidal Behavior and Ideation: Antiepileptic drugs (AEDs), including APTIOM, increase the risk of suicidal thoughts or behavior. Anyone considering prescribing APTIOM or any other AED must balance this risk with the risk of untreated illness. Epilepsy and many other illnesses for which AEDs are prescribed are themselves associated with morbidity and mortality and an increased risk of suicidal thoughts and behavior. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Patients and caregivers should also be advised to be alert to these behavioral changes and to immediately report them to the healthcare provider.

Serious Dermatologic Reactions, including Stevens-Johnson Syndrome (SJS), have been reported in association with APTIOM use. Serious and sometimes fatal dermatologic reactions, including toxic epidermal necrolysis (TEN) and SJS, have been reported in patients using oxcarbazepine or carbamazepine, which are chemically related to APTIOM. Should a patient develop a dermatologic reaction while using APTIOM, discontinue APTIOM use unless it is clearly not drug related.

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), also known as **Multiorgan Hypersensitivity**, has been reported in patients taking APTIOM. DRESS typically, although not exclusively, presents with fever, rash, and/or lymphadenopathy, in association with other organ system involvement. If this reaction is suspected, treatment with APTIOM should be discontinued.

Anaphylactic Reactions and Angioedema: Rare cases of anaphylaxis and angioedema have been reported in patients taking APTIOM. Anaphylaxis and angioedema associated with laryngeal edema can be fatal. If a patient develops any of these reactions, the drug should be discontinued. Patients with a prior anaphylactic-type reaction after treatment with either oxcarbazepine or APTIOM should not be treated with APTIOM.

Hyponatremia: Clinically significant hyponatremia (sodium <125 mEq/L) can develop in patients taking APTIOM. In the controlled epilepsy trials, 1.0% (800 mg) and 1.5% (1200 mg) of patients treated with APTIOM had at least one serum sodium level value less than 125 mEq/L, compared to none on placebo. These effects were dose related and generally appeared within the first 8 weeks of treatment (as early as after 3 days). Measurement of serum sodium and chloride levels should be considered during maintenance treatment with APTIOM, particularly if the patient is receiving other medications known to decrease serum sodium levels.

Neurological Adverse Reactions: APTIOM causes dose-dependent increases in the following reactions (dizziness, disturbance in gait and coordination, somnolence, fatigue, cognitive dysfunction, and visual changes) compared to placebo. These events were more often serious in APTIOM-treated patients than placebo. There was an increased risk of dizziness, disturbance in gait and coordination, and visual changes during the titration period (compared to the maintenance period), and there may be an increased risk of these adverse reactions in patients 60 years of age and older compared to younger adults. The incidences of dizziness and diplopia were greater with concomitant use of APTIOM and carbamazepine compared to the use of APTIOM without carbamazepine. Prescribers should advise patients against engaging in hazardous activities requiring mental alertness, such as operating motor vehicles or dangerous machinery, until the effect of APTIOM is known.

Withdrawal of AEDs: As with all AEDs, APTIOM should be withdrawn gradually because of the risk of increased seizure frequency and status epilepticus.

Drug Induced Liver Injury: Hepatic effects, ranging from mild to moderate elevations in transaminases (>3 times the upper limit of normal) to rare cases with concomitant elevations of total bilirubin (>2 times the upper limit of normal) have been reported with APTIOM use. Baseline evaluations of liver laboratory tests are recommended. APTIOM should be discontinued in patients with jaundice or other evidence of significant liver injury.

Abnormal Thyroid Function Tests: Dose-dependent decreases in serum T3 and T4 (free and total) values have been observed in patients taking APTIOM. These changes were not associated with other abnormal thyroid function tests suggesting hypothyroidism. Abnormal thyroid function tests should be clinically evaluated.

Adverse Reactions: The most frequently reported adverse reactions in patients receiving APTIOM at doses of 800 mg or 1200 mg (≥4% and ≥2% greater than placebo) were dizziness, somnolence, nausea, headache, diplopia, vomiting, fatigue, vertigo, ataxia, blurred vision, and tremor.

Dosing Considerations

When APTIOM and carbamazepine are taken concomitantly, the dose of APTIOM or carbamazepine may need to be adjusted based on efficacy and tolerability. APTIOM should not be taken as an adjunctive therapy with oxcarbazepine. For patients taking other enzyme-inducing AEDs (i.e., phenobarbital, phenytoin, and primidone), higher doses of APTIOM may be needed.

A dose reduction is recommended in patients with moderate and severe renal impairment (i.e., creatinine clearance <50 mL/min).

Dose adjustments are not required in patients with mild to moderate hepatic impairment. Use of APTIOM in patients with severe hepatic impairment has not been studied, and use in these patients is not recommended.

Concomitant use of APTIOM and oral contraceptives containing ethinylestradiol and levonorgestrel is associated with lower plasma levels of these hormones. Patients should use additional or alternative non-hormonal birth control during APTIOM treatment and after discontinuation of APTIOM for one menstrual cycle, or until otherwise instructed.

Please see Brief Summary of Full Prescribing Information on adjacent pages.

References: 1. APTIOM [prescribing information]. Sunovion Pharmaceuticals Inc., Marlborough, MA, November 2013. 2. Data on file, Sunovion Pharmaceuticals Inc.

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Aptiom®
(eslicarbazepine acetate) tablets
200 mg • 400 mg • 600 mg • 800 mg

Aptiom
(eslicarbazepine acetate) tablets
200 mg · 400 mg · 600 mg · 800 mg

BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION

INDICATIONS AND USAGE

Partial-Onset Seizures

APTIOM (eslicarbazepine acetate) is indicated as adjunctive treatment of partial-onset seizures.

CONTRAINDICATIONS

APTIOM is contraindicated in patients with a hypersensitivity to eslicarbazepine acetate or oxcarbazepine.

WARNINGS AND PRECAUTIONS

Suicidal Behavior and Ideation

Antiepileptic drugs (AEDs), including APTIOM, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior.

Pooled analyses of 199 placebo-controlled clinical trials (mono- and adjunctive therapy) of 11 different AEDs showed that patients randomized to one of the AEDs had approximately twice the risk (adjusted Relative Risk 1.8, 95% confidence interval [CI]: 1.2, 2.7) of suicidal thinking or behavior compared to patients randomized to placebo. In these trials, which had a median treatment duration of 12 weeks, the estimated incidence of suicidal behavior or ideation among 27,863 AED-treated patients was 0.43%, compared to 0.24% among 16,029 placebo-treated patients, representing an increase of approximately one case of suicidal thinking or behavior for every 530 patients treated. There were four suicides in drug-treated patients in the trials and none in placebo-treated patients, but the number of events is too small to allow any conclusion about drug effect on suicide.

The increased risk of suicidal thoughts or behavior with AEDs was observed as early as one week after starting treatment with AEDs and persisted for the duration of treatment assessed. Because most trials included in the analysis did not extend beyond 24 weeks, the risk of suicidal thoughts or behavior beyond 24 weeks could not be assessed.

The risk of suicidal thoughts or behavior was generally consistent among drugs in the data analyzed. The finding of increased risk with AEDs of varying mechanisms of action and across a range of indications suggests that the risk applies to all AEDs used for any indication. The risk did not vary substantially by age (5-100 years) in the clinical trials analyzed.

Table 2 shows absolute and relative risk by indication for all evaluated AEDs.

Table 2: Risk of Suicidal Thoughts or Behaviors by Indication for Antiepileptic Drugs in the Pooled Analysis

Indication	Placebo Patients with Events Per 1000 Patients	Drug Patients with Events Per 1000 Patients	Relative Risk: Incidence of Events in Drug Patients/ Incidence in Placebo Patients	Risk Difference: Additional Drug Patients with Events Per 1000 Patients
Epilepsy	1.0	3.4	3.5	2.4
Psychiatric	5.7	8.5	1.5	2.9
Other	1.0	1.9	1.9	0.9
Total	2.4	4.3	1.8	1.9

The relative risk for suicidal thoughts or behavior was higher in clinical trials in patients with epilepsy than in clinical trials in patients with psychiatric or other conditions, but the absolute risk differences were similar for epilepsy and psychiatric indications.

Anyone considering prescribing APTIOM or any other AED must balance this risk with the risk of untreated illness. Epilepsy and many other illnesses for which AEDs are prescribed are themselves associated with morbidity and mortality and an increased risk of suicidal thoughts and behavior. Should suicidal thoughts and behavior emerge during treatment, the prescriber needs to consider whether the emergence of these symptoms in any given patient may be related to the illness being treated.

Patients, their caregivers, and families should be informed that AEDs increase the risk of suicidal thoughts and behavior and should be advised of the need to be alert for the emergence or worsening of the signs and symptoms of depression, any unusual changes in mood or behavior, or the emergence of suicidal thoughts, behavior, or thoughts about self-harm. Behaviors of concern should be reported immediately to healthcare providers.

Serious Dermatologic Reactions

Serious dermatologic reactions including Stevens-Johnson Syndrome (SJS) have been reported in association with APTIOM use. Serious and sometimes fatal dermatologic reactions, including toxic epidermal necrolysis (TEN) and SJS, have been reported in patients using oxcarbazepine or carbamazepine which are chemically related to APTIOM. The reporting rate of these reactions associated with oxcarbazepine use exceeds the background incidence rate estimates by a factor of 3- to 10-fold. Risk factors for development of serious dermatologic reactions with APTIOM use have not been identified.

If a patient develops a dermatologic reaction while taking APTIOM, discontinue APTIOM use, unless the reaction is clearly not drug-related. Patients with a prior dermatologic reaction with either oxcarbazepine or APTIOM should not be treated with APTIOM.

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)/Multiorgan Hypersensitivity

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), also known as Multiorgan Hypersensitivity, has been reported in patients taking APTIOM. DRESS may be fatal or life-threatening. DRESS typically, although not exclusively, presents with fever, rash, and/or lymphadenopathy, in association with other organ system involvement, such as hepatitis, nephritis, hematological abnormalities, myocarditis, or myositis sometimes resembling an acute viral infection. Eosinophilia is often present. Because this disorder is variable in its expression, other organ systems not noted here may be involved. It is important to note that early manifestations of hypersensitivity, such as fever or lymphadenopathy, may be present even though rash is not evident. If such signs or symptoms are present, the patient should be evaluated immediately. APTIOM should be discontinued and not be resumed if an alternative etiology for the signs or symptoms cannot be established. Patients with a prior DRESS reaction with either oxcarbazepine or APTIOM should not be treated with APTIOM.

Anaphylactic Reactions and Angioedema

Rare cases of anaphylaxis and angioedema have been reported in patients taking APTIOM. Anaphylaxis and angioedema associated with laryngeal edema can be fatal. If a patient develops any of these reactions after treatment with APTIOM, the drug should be discontinued. Patients with a prior anaphylactic-type reaction with either oxcarbazepine or APTIOM should not be treated with APTIOM.

Hyponatremia

Clinically significant hyponatremia (sodium <125 mEq/L) can develop in patients taking APTIOM. In the controlled epilepsy trials, 4/413 patients (1.0%) treated with 800 mg and 8/410 (1.5%) patients treated with 1200 mg of APTIOM had at least one serum sodium value less than 125 mEq/L, compared to none of the patients assigned to placebo. A higher percentage of APTIOM-treated patients (5.1%) than placebo-treated patients (0.7%) experienced decreases in sodium values of more than 10 mEq/L. These effects were dose-related and generally appeared within the first 6 weeks of treatment (as early as after 3 days). Serious, life-threatening complications were reported with APTIOM-associated hyponatremia (as low as 112 mEq/L) including seizures, severe nausea/vomiting leading to dehydration, severe gait instability, and injury. Some patients required hospitalization and discontinuation of APTIOM. Concurrent hypochloremia was also present in patients with hyponatremia. Depending on the severity of hyponatremia, the dose of APTIOM may need to be reduced or discontinued.

Measurement of serum sodium and chloride levels should be considered during maintenance treatment with APTIOM, particularly if the patient is receiving other medications known to decrease serum sodium levels and should be performed if symptoms of hyponatremia develop (e.g., nausea/vomiting, malaise, headache, lethargy, confusion, irritability, muscle weakness/spasms, obtundation, or increase in seizure frequency or severity).

Neurological Adverse Reactions

Dizziness and Disturbance in Gait and Coordination

APTIOM causes dose-related increases in adverse reactions related to dizziness and disturbance in gait and coordination (dizziness, ataxia, vertigo, balance disorder, gait disturbance, nystagmus, and abnormal coordination). In controlled epilepsy trials, these events were reported in 28% and 36% of patients randomized to receive APTIOM at doses of 800 mg and 1200 mg/day, respectively, compared to 12% of placebo-treated patients. Events related to dizziness and disturbance in gait and coordination were more often serious in APTIOM-treated patients than in placebo-treated patients (2% vs. 0%), and more often led to study withdrawal in APTIOM-treated patients than in placebo-treated patients (9% vs. 0.7%). There was an increased risk of these adverse reactions during the titration period (compared to the maintenance period) and there also may be an increased risk of these adverse reactions in patients 60 years of age and older compared to younger adults. Nausea and vomiting also occurred with these events.

The incidence of dizziness was greater with the concomitant use of APTIOM and carbamazepine compared to the use of APTIOM without carbamazepine (up to 27% vs. 19%, respectively). Therefore, consider dosage modifications of both APTIOM and carbamazepine if these drugs are used concomitantly.

Somnolence and Fatigue

APTIOM causes dose-dependent increases in somnolence and fatigue-related adverse reactions (fatigue, asthenia, malaise, hypersomnia, sedation, and lethargy). In the controlled epilepsy trials, these events were reported in 13% of placebo patients, 16% of patients randomized to receive 800 mg/day APTIOM, and 28% of patients randomized to receive 1200 mg/day APTIOM. Somnolence and fatigue-related events were serious in 0.8% of APTIOM-treated patients (and 0 placebo patients) and led to discontinuation in 2% of APTIOM-treated patients (and 0.7% of placebo-treated patients).

Cognitive Dysfunction

APTIOM causes dose-dependent increases in cognitive dysfunction-related events (memory impairment, disturbance in attention, amnesia, confusional state, aphasia, speech disorder, slowness of thought, disorientation, and psychomotor retardation). In the controlled epilepsy trials, these events were reported in 1% of placebo patients, 4% of patients randomized to receive 800 mg/day APTIOM, and 7% of patients randomized to receive 1200 mg/day APTIOM. Cognitive dysfunction-related events were serious in 0.2% of APTIOM-treated patients (and 0.2% of placebo patients) and led to discontinuation in 1% of APTIOM-treated patients (and 0.3% of placebo-treated patients).

Visual Changes

APTIOM causes dose-dependent increases in events related to visual changes including diplopia, blurred vision, and impaired vision. In the controlled epilepsy trials, these events were reported in 16% of patients randomized to receive APTIOM compared to 6% of placebo patients. Eye events were serious in 0.7% of APTIOM-treated patients (and 0 placebo patients) and led to discontinuation in 4% of APTIOM-treated patients (and 0.2% of placebo-treated patients). There was an increased risk of these adverse reactions during the titration period (compared to the maintenance period) and also in patients 60 years of age and older (compared to younger adults). The incidence of diplopia was greater with the concomitant use of APTIOM and carbamazepine compared to the use of APTIOM without carbamazepine (up to 16% vs. 8%, respectively).

Hazardous Activities

Prescribers should advise patients against engaging in hazardous activities requiring mental alertness, such as operating motor vehicles or dangerous machinery, until the effect of APTIOM is known.

Withdrawal of AEDs

As with all antiepileptic drugs, APTIOM should be withdrawn gradually because of the risk of increased seizure frequency and status epilepticus.

Drug Induced Liver Injury

Hepatic effects, ranging from mild to moderate elevations in transaminases (>3 times the upper limit of normal) to rare cases with concomitant elevations of total bilirubin (>2 times the upper limit of normal) have been reported with APTIOM use. Baseline evaluations of liver laboratory tests are recommended. The combination of transaminase elevations and elevated bilirubin without evidence of obstruction is generally recognized as an important predictor of severe liver injury. APTIOM should be discontinued in patients with jaundice or other evidence of significant liver injury (e.g., laboratory evidence).

Abnormal Thyroid Function Tests

Dose-dependent decreases in serum T3 and T4 (free and total) values have been observed in patients taking APTIOM. These changes were not associated with other abnormal thyroid function tests suggesting hypothyroidism. Abnormal thyroid function tests should be clinically evaluated.

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In all controlled and uncontrolled trials in patients with partial-onset seizures, 1195 patients received APTIOM of whom 868 were treated for longer than 6 months and 462 for longer than 12 months. In the placebo controlled trials in patients with partial-onset seizures, 1021 patients received APTIOM. Of the patients in these trials, approximately 95% were between 18 and 60 years old, approximately 59% were male, and approximately 80% were Caucasian.

Adverse Reactions Leading to Discontinuation

In the controlled epilepsy trials (Studies 1, 2, and 3), the rate of discontinuation as a result of any adverse reaction was 14% for the 800 mg dose, 25% for the 1200 mg dose, and 7% in subjects randomized to placebo. The adverse reactions most commonly (≥1% in any APTIOM treatment group, and greater than placebo) leading to discontinuation, in descending order of frequency, were dizziness, nausea, vomiting, ataxia, diplopia, somnolence, headache, blurred vision, vertigo, asthenia, fatigue, rash, dysarthria, and tremor.

Most Common Adverse Reactions

The most frequently reported adverse reactions in patients receiving APTIOM at doses of 800 mg or 1200 mg (≥4% and ≥2% greater than placebo) were dizziness, somnolence, nausea, headache, diplopia, vomiting, fatigue, vertigo, ataxia, blurred vision, and tremor.

Table 3 gives the incidence of adverse reactions that occurred in ≥2% of subjects with partial-onset seizures in any APTIOM treatment group and for which the incidence was greater than placebo during the controlled clinical trials. Adverse reactions during titration were less frequent for patients who began therapy at an initial dose of 400 mg for 1 week and then increased to 800 mg compared to patients who initiated therapy at 800 mg.

Table 3: Adverse Reactions Incidence in Pooled Controlled Clinical Trials of Adjunctive Therapy in Adults (Events ≥2% of Patients in the APTIOM 800 mg or 1200 mg Dose Group and More Frequent Than in the Placebo Group)

	Placebo	APTIOM	
		800 mg	1200 mg
	(N=526) %	(N=413) %	(N=410) %
Ear and labyrinth disorders			
Vertigo	<1	2	5
Eye disorders			
Diplopia	2	9	11
Blurred vision	1	6	5
Visual impairment	1	2	1
Gastrointestinal disorders			
Nausea	5	10	16
Vomiting	3	9	10
Diarrhea	3	4	2
Constipation	1	2	2
Abdominal pain	1	2	2
Gastritis	<1	2	<1
General disorders and administration site conditions			
Fatigue	4	4	7
Asthenia	2	2	3
Gait disturbance	<1	2	2
Peripheral edema	1	2	1
Infections and infestations			
Urinary tract infections	1	2	2
Injury, poisoning and procedural complications			
Fall	1	3	1
Metabolism and nutrition disorders			
Hypokalemia	<1	2	2
Nervous system disorders			
Dizziness	9	20	28
Somnolence	8	11	16
Headache	9	13	15
Ataxia	2	4	6
Balance disorder	<1	3	3
Tremor	1	2	4
Dysarthria	0	1	2
Memory impairment	<1	1	2
Nystagmus	<1	1	2
Psychiatric disorders			
Depression	2	1	3
Insomnia	1	2	2
Respiratory, thoracic and mediastinal disorders			
Cough	1	2	1
Skin and subcutaneous tissue disorders			
Rash	1	1	3
Vascular disorders			
Hypertension	1	1	2

Other Adverse Reactions with APTIOM Use

Compared to placebo, APTIOM use was associated with slightly higher frequencies of decreases in hemoglobin and hematocrit, increases in total cholesterol, triglycerides, and LDL, and increases in creatine phosphokinase.

Adverse Reactions Based on Gender and Race

No significant gender differences were noted in the incidence of adverse reactions. Although there were few non-Caucasian patients, no differences in the incidences of adverse reactions compared to Caucasian patients were observed.

DRUG INTERACTIONS

General Information

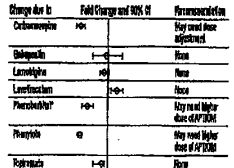
Several AEDs (e.g., carbamazepine, phenobarbital, phenytoin, and primidone) can induce enzymes that metabolize APTIOM and can cause decreased plasma concentrations of eslicarbazepine (see Figure 1).

APTIOM can inhibit CYP2C19, which can cause increased plasma concentrations of drugs that are metabolized by this isoenzyme (e.g., phenytoin, clobazam, and omeprazole). *In vivo* studies suggest that APTIOM can induce CYP3A4, decreasing plasma concentrations of drugs that are metabolized by this isoenzyme (e.g., simvastatin) (see Figure 2).

Potential for Other AEDs to Affect Eslicarbazepine

The potential impact of other AEDs on the systemic exposure (area under the curve, AUC) of eslicarbazepine, the active metabolite of APTIOM, is shown in Figure 1:

Figure 1: Potential Impact of Other AEDs on AUC of Eslicarbazepine



Potential for APTIOM to Affect Other Drugs

The potential impact of APTIOM on the systemic exposure (AUC) of other drugs (including AEDs) is shown in Figure 2:

Figure 2: Potential Impact of APTIOM on the AUC of AEDs

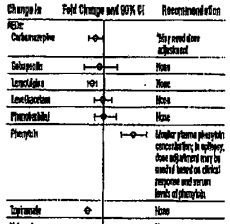
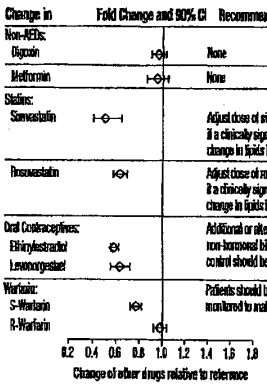


Figure 2b: Potential Impact of APTIOM on the AUC of Non-AEDs



Oral Contraceptives
Because concomitant use of APTIOM and ethinylestradiol and levonorgestrel is associated with lower plasma levels of these hormones, females of reproductive potential should use additional or alternative non-hormonal birth control.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category C
There are no adequate and well-controlled studies in pregnant women. In oral studies conducted in pregnant mice, rats, and rabbits, eslicarbazepine acetate demonstrated developmental toxicity, including teratogenicity (mice), embryolethality (rats), and fetal growth retardation, at clinically relevant doses. APTIOM should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

When eslicarbazepine acetate was orally administered (150, 350, 650 mg/kg/day) to pregnant mice throughout organogenesis, increased incidences of fetal malformations was observed at all doses and fetal growth retardation was observed at the mid and high doses. A no-effect dose for adverse developmental effects was not identified. At the lowest dose tested, plasma eslicarbazepine exposure (C_{max}, AUC) is less than that in humans at the maximum recommended human dose (MRHD) of 1200 mg/day.

Oral administration of eslicarbazepine acetate (40, 160, 320 mg/kg/day) to pregnant rabbits throughout organogenesis resulted in fetal growth retardation and increased incidences of skeletal variations at the mid and high doses. The no-effect dose (40 mg/kg/day) is less than the MRHD on a mg/m² basis.

Oral administration to pregnant rats (65, 125, 250 mg/kg/day) throughout organogenesis resulted in embryolethality at all doses, increased incidences of skeletal variations at the mid and high doses, and fetal growth retardation at the high dose. The lowest dose tested (65 mg/kg/day) is less than the MRHD on a mg/m² basis.

When eslicarbazepine acetate was orally administered to female mice during pregnancy and lactation (150, 350, 650 mg/kg/day), the gestation period was prolonged at the highest dose tested. In offspring, a persistent reduction in offspring body weight and delayed physical development and sexual maturation were observed and the mid and high doses. The lowest dose tested (150 mg/kg/day) is less than the MRHD on a mg/m² basis.

When eslicarbazepine acetate was orally administered (65, 125, 250 mg/kg/day) to rats during pregnancy and lactation, reduced offspring body weight was seen at the mid and high doses. Delayed sexual maturation and a neurological deficit (decreased motor coordination) were observed at the highest dose tested. The no-effect dose for adverse developmental effects (65 mg/kg/day) is less than the MRHD on a mg/m² basis.

The rat data are of uncertain relevance to humans because of differences in metabolic profile between species.

Pregnancy Registry
Physicians are advised to recommend that pregnant patients taking APTIOM enroll in the North American Antiepileptic Drug Pregnancy Registry. This can be done by calling 1-888-233-2334 (toll-free), and must be done by patients themselves. Information on the registry can also be found at the website http://www.aedpregnancyregistry.org/.

Nursing Mothers
Eslicarbazepine is excreted in human milk. Because of the potential for serious adverse reactions in nursing infants from APTIOM, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use
Safety and effectiveness in patients below 18 years of age have not been established.

In a juvenile animal study in which eslicarbazepine acetate (40, 60, 160 mg/kg/day) was orally administered to young dogs for 10 months starting on postnatal day 21, mortality and evidence of immunotoxicity (bone marrow hypocellularity and lymphoid tissue depletion) were observed at all doses. Convulsions were seen at the highest dose tested. Adverse effects on bone growth (decreased bone mineral content and density) were seen in females at all doses at the end of the dosing period, but not at the end of a 2-month recovery period. None of these findings were reported in adult dogs dosed with eslicarbazepine acetate for up to 12 months in duration. A no-effect dose for adverse effects on juvenile dogs was not identified.

Geriatric Use
There were insufficient numbers of patients ≥65 years old enrolled in the controlled epilepsy trials (N=15) to determine the efficacy of APTIOM in this patient population. The pharmacokinetics of APTIOM were evaluated in elderly healthy subjects (N=12). Although the pharmacokinetics of eslicarbazepine are not affected by age independently, dose selection should take in consideration the greater frequency of renal impairment and other concomitant medical conditions and drug therapies in the elderly patient. Dose adjustment is necessary if CrCl is <50 mL/min.

Patients with Renal Impairment
Clearance of eslicarbazepine is decreased in patients with impaired renal function and is correlated with creatinine clearance. Dosage adjustment is necessary in patients with CrCl<50 mL/min.

Patients with Hepatic Impairment
Dose adjustments are not required in patients with mild to moderate hepatic impairment. Use of APTIOM in patients with severe hepatic impairment has not been evaluated, and use in these patients is not recommended.

DRUG ABUSE AND DEPENDENCE

Controlled Substance
APTIOM is not a controlled substance.

Abuse
Prescription drug abuse is the intentional non-therapeutic use of a drug, even once, for its rewarding psychological or physiological effects. Drug addiction, which develops after repeated drug abuse, is characterized by a strong desire to take a drug despite harmful consequences, difficulty in controlling its use, giving a higher priority to drug use than to obligations, increased tolerance, and sometimes physical withdrawal. Drug abuse and drug addiction are separate and distinct from physical dependence (for example, abuse may not be accompanied by physical dependence).

In a human abuse study in recreational sedative abusers APTIOM showed no evidence of abuse. In Phase 1, 1.5% of the healthy volunteers taking APTIOM reported euphoria compared to 0.4% taking placebo.

Dependence
Physical dependence is characterized by withdrawal symptoms after abrupt discontinuation or a significant dose reduction of a drug.

The potential for APTIOM to produce withdrawal symptoms has not been adequately evaluated. In general, antiepileptic drugs should not be abruptly discontinued in patients with epilepsy because of the risk of increased seizure frequency and status epilepticus.

OVERDOSAGE

Signs, Symptoms, and Laboratory Findings of Acute Overdose in Humans
Symptoms of overdose are consistent with the known adverse reactions of APTIOM and include hyponatremia (sometimes severe), dizziness, nausea, vomiting, somnolence, euphoria, oral paraesthesia, ataxia, walking difficulties, and diplopia.

Treatment or Management of Overdose
There is no specific antidote for overdose with APTIOM. Symptomatic and supportive treatment should be administered as appropriate. Removal of the drug by gastric lavage and/or inactivation by administering activated charcoal should be considered.

Standard hemodialysis procedures result in partial clearance of APTIOM. Hemodialysis may be considered based on the patient's clinical state or in patients with significant renal impairment.

PATIENT COUNSELING INFORMATION

See FDA-approved Medication Guide and Patient Counseling Information section in the Full Prescribing Information.

SUNOVION

Manufactured for:
Sunovion Pharmaceuticals Inc.
Marlborough, MA 01752 USA

Under license from BIAL

November 2013
2/14 APT080-14

United States of America
United States Patent and Trademark Office

Bial

Reg. No. 4,490,162

Registered Mar. 4, 2014

Int. Cls.: 5 and 42

TRADEMARK

SERVICE MARK

PRINCIPAL REGISTER

BIAL-PORTELA & CA., S.A. (PORTUGAL SOCIEDAD ANONIMA (SA))
APARTADO 19
A. AVENIDA DA SIDERURGIA NACIONAL
SAO MAMEDE CORONADO, PORTUGAL 4745-457

FOR: PHARMACEUTICAL PREPARATIONS FOR THE TREATMENT OF CARDIOVASCULAR DISEASES, UROLOGICAL DISORDERS, GASTROINTESTINAL DISORDERS, ALLERGIES, DIABETES, HYPERTENSION, ERECTILE DYSFUNCTION, SEXUAL DYSFUNCTION, STROKE, CANCER, MIGRAINES, OBESITY AND RESPIRATORY DISEASES, FUNGAL DISORDERS; PHARMACEUTICAL PREPARATIONS, NAMELY, ANTI-INFLAMMATORY ANALGESICS; PHARMACEUTICAL PREPARATIONS, NAMELY, CHOLESTEROL REDUCERS, SMOKING CESSATION PREPARATIONS, TISSUE AND SKIN REPAIR PREPARATIONS; PHARMACEUTICAL PREPARATIONS, NAMELY, DECONGESTANTS AND ANTIHISTAMINES; PHARMACEUTICAL PREPARATIONS FOR THE TREATMENT OF PAINS, COUGH, FEVER, ANGINA, OTORHINOLARYNGOLOGICAL DISEASES, GASTRIC AND LIVER ILLNESSES, HEART ILLNESSES, ARTERIAL AND VENOUS ILLNESSES, RHEUMATIC ILLNESSES; ANAESTHETICS; ANALGESICS; FROSTBITE SALVE FOR PHARMACEUTICAL PURPOSES; HEMORRHOID TREATMENT PREPARATIONS; PHARMACEUTICAL PREPARATIONS FOR THE TREATMENT OF HEADACHES; MEDICINES FOR ALLEVIATING CONSTIPATION; CONTRACEPTIVE PREPARATIONS; RADIOLOGICAL CONTRAST SUBSTANCES FOR MEDICAL PURPOSES; DIAGNOSTIC PREPARATIONS FOR MEDICAL PURPOSES; PHARMACEUTICALS FOR THE TREATMENT OF PAIN, FEVER, ANGINA, OTORHINOLARYNGOLOGICAL DISEASES, GASTRIC AND LIVER ILLNESSES, HEART ILLNESSES, ARTERIAL AND VENOUS ILLNESSES, RHEUMATIC ILLNESSES; PHARMACEUTICAL PREPARATIONS FOR THE TREATMENT OF DIABETES, CANCER; PHARMACEUTICAL PREPARATIONS FOR THE PREVENTION AND TREATMENT OF CANCER, CARCINOMAS AND SARCOMAS; PHARMACEUTICAL PREPARATIONS FOR THE PREVENTION AND TREATMENT OF TUMOURS OF ANY DESCRIPTION; PHARMACEUTICAL PREPARATIONS, NAMELY, PLATELET STIMULATING FACTORS; PHARMACEUTICAL PREPARATIONS FOR THE TREATMENT OF THE CENTRAL NERVOUS SYSTEM, NAMELY, ENCEPHALITIS, EPILEPSY, BIPOLAR DISORDER, NEUROPATHIC PAIN, MIGRAINE, GENERALIZED ANXIETY DISORDER, SOCIAL PHOBIA, DIABETIC NEUROPATHIES, PANIC DISORDER, POSTOPERATIVE PAIN, BACK PAIN, FIBROMYALGIA, AND POSTHERPETIC NEURALGIA, POST-TRAUMATIC STRESS DISORDER, PARKINSON'S DISEASE, ALZHEIMERS; PHARMACEUTICAL PREPARATIONS FOR THE TREATMENT OF PSYCHIATRIC DISEASES, NAMELY, SCHIZOPHRENIA, ANXIETY DISORDERS, MOOD DISORDERS, COGNITIVE DISORDERS, DEPRESSION, MANIA;

Michelle K. Lee

Deputy Director of the United States Patent and Trademark Office

Reg. No. 4,490,162 PHARMACEUTICAL PREPARATIONS AND SUBSTANCES FOR THE PREVENTION AND TREATMENT OF DISEASES AND DISORDERS OF THE RESPIRATORY SYSTEM; PHARMACEUTICAL PREPARATIONS FOR TREATMENT OF GOUT, NAMELY, BRONCHODILATORS AND ANTI-ASTHMATIC PREPARATIONS; PHARMACEUTICAL PREPARATIONS AND SUBSTANCES FOR THE PREVENTION AND TREATMENT OF DISEASES AND DISORDERS OF THE PERIPHERAL NERVOUS SYSTEM, CARDIOVASCULAR SYSTEM, GASTRO-INTESTINAL SYSTEM; PRESCRIPTION PHARMACEUTICAL PREPARATIONS AND SUBSTANCES FOR USE IN PAIN CONTROL, ANAESTHESIA, ONCOLOGY; PRESCRIPTION PHARMACEUTICAL PREPARATIONS AND SUBSTANCES FOR THE TREATMENT AND PREVENTION OF DIABETES; PHARMACEUTICAL PREPARATIONS AND SUBSTANCES, NAMELY, ANTIBIOTICS, ANTIVIRALS, ANTIDIABETIC PREPARATIONS, NONDEPOLARIZING SKELETAL NEUROMUSCULAR BLOCKING AGENTS, HEMOSTATIC AGENTS, EXPECTORANTS, ANTI-LEUKEMIA AGENTS, ANTI-ARRHYTHMICS, DERMATOLOGICALS AND VASOPRESSORS; PHARMACEUTICAL PREPARATIONS AND SUBSTANCES FOR THE TREATMENT OF CANCER, HIV, OBESITY, AND RESPIRATORY AND UROLOGIC DISORDERS AND DISEASES; PHARMACEUTICAL PREPARATIONS AND SUBSTANCES FOR THE TREATMENT OF ACUTE ISCHEMIC STROKE AND TRAUMATIC BRAIN INJURY (TBI); CEREBRAL VASODILATORS; PHARMACEUTICAL PREPARATIONS FOR THE TREATMENT OF SMOOTH MUSCLE DISORDERS, HEADACHES, WRINKLES, HYPERHYDROSIS, SPORTS INJURIES, NAMELY, INJURED OR TORN SKIN, MUSCLE, LIGAMENTS OR BONE, TREMORS, NAMELY, SPASMODIC SMOOTH, STRIATED OR CARDIAC MUSCLES, AND PAIN, NAMELY, SMOOTH MUSCLE PAIN, STRIATED MUSCLE PAIN, CARDIAC MUSCLE PAIN, NEUROPATHIC PAIN, INFLAMMATORY PAIN, VISCERAL PAIN, CHRONIC PAIN, ACUTE PAIN, TRAUMATIC INJURY PAIN, REFERRED PAIN, GROWING PAIN, HUNGER PAIN, INTRACTABLE PAIN, LABOUR PAIN, ORGANIC PAIN, PHANTOM LIMB PAIN, POSTPRANDIAL PAIN, PSYCHOGENIC PAIN, BACK PAIN, POST-STROKE PAIN, CANCER PAIN, NOCICEPTIVE PAIN, HEADACHE PAIN, PROSTATIC PAIN, AND BLADDER PAIN; PHARMACEUTICAL PREPARATIONS FOR THE TREATMENT OF MUSCLE DYSTONIAS, NERVE DISORDERS, AND SPASMODIC STRIATED, SMOOTH OR CARDIAC MUSCLES; PHARMACEUTICAL PREPARATIONS FOR THE TREATMENT OF CEREBRAL PALSY; PHARMACEUTICAL PREPARATIONS, NAMELY, MUSCLE RELAXANTS AND ANTI-EMETICS, XANTHINE OXIDASE INHIBITORS; PHARMACEUTICAL PREPARATIONS, NAMELY, SCABICIDES, ANTI-MALARIALS, IN CLASS 5 (U.S. CLS. 6, 18, 44, 46, 51 AND 52).

FOR: PHARMACEUTICAL, MEDICAL AND BIOLOGICAL RESEARCH AND DEVELOPMENT IN THE FIELD OF HUMAN THERAPEUTICS; CONDUCTING OF PRE-CLINICAL AND CLINICAL TEST RESEARCH IN THE PHARMACEUTICAL AND MEDICAL FIELDS; SCIENTIFIC RESEARCH AND DEVELOPMENT IN THE FIELD OF HUMAN MEDICINE, IN CLASS 42 (U.S. CLS. 100 AND 101).

OWNER OF PORTUGAL REG. NO. 380508, DATED 8-13-2004, EXPIRES 8-13-2014.

THE MARK CONSISTS OF THE STYLIZED LETTERS "BIAL".

SER. NO. 85-583,401, FILED 3-29-2012.

BARBARA GAYNOR, EXAMINING ATTORNEY

REQUIREMENTS TO MAINTAIN YOUR FEDERAL TRADEMARK REGISTRATION

WARNING: YOUR REGISTRATION WILL BE CANCELLED IF YOU DO NOT FILE THE DOCUMENTS BELOW DURING THE SPECIFIED TIME PERIODS.

Requirements in the First Ten Years*
What and When to File:

First Filing Deadline: You must file a Declaration of Use (or Excusable Nonuse) between the 5th and 6th years after the registration date. *See* 15 U.S.C. §§1058, 1141k. If the declaration is accepted, the registration will continue in force for the remainder of the ten-year period, calculated from the registration date, unless cancelled by an order of the Commissioner for Trademarks or a federal court.

Second Filing Deadline: You must file a Declaration of Use (or Excusable Nonuse) **and** an Application for Renewal between the 9th and 10th years after the registration date.* *See* 15 U.S.C. §1059.

Requirements in Successive Ten-Year Periods*
What and When to File:

You must file a Declaration of Use (or Excusable Nonuse) **and** an Application for Renewal between every 9th and 10th-year period, calculated from the registration date.*

Grace Period Filings*

The above documents will be accepted as timely if filed within six months after the deadlines listed above with the payment of an additional fee.

The United States Patent and Trademark Office (USPTO) will NOT send you any future notice or reminder of these filing requirements.

***ATTENTION MADRID PROTOCOL REGISTRANTS:** The holder of an international registration with an extension of protection to the United States under the Madrid Protocol must timely file the Declarations of Use (or Excusable Nonuse) referenced above directly with the USPTO. The time periods for filing are based on the U.S. registration date (not the international registration date). The deadlines and grace periods for the Declarations of Use (or Excusable Nonuse) are identical to those for nationally issued registrations. *See* 15 U.S.C. §§1058, 1141k. However, owners of international registrations do not file renewal applications at the USPTO. Instead, the holder must file a renewal of the underlying international registration at the International Bureau of the World Intellectual Property Organization, under Article 7 of the Madrid Protocol, before the expiration of each ten-year term of protection, calculated from the date of the international registration. *See* 15 U.S.C. §1141j. For more information and renewal forms for the international registration, see http://www.wipo.int/madrid/en/.

NOTE: Fees and requirements for maintaining registrations are subject to change. Please check the USPTO website for further information. With the exception of renewal applications for registered extensions of protection, you can file the registration maintenance documents referenced above online at http://www.uspto.gov.

United States of America
United States Patent and Trademark Office

SUNOVION

Reg. No. 4,096,601

Registered Feb. 7, 2012

Int. Cl.: 5

TRADEMARK

PRINCIPAL REGISTER

DAINIPPON SUMITOMO PHARMA CO., LTD. (JAPAN CORPORATION)
6-8, DOSHOMACHI 2-CHOME, CHUO-KU
OSAKA-SHI, OSAKA, JAPAN

FOR: PHARMACEUTICAL PREPARATIONS, NAMELY, ANTI-INFLAMMATORIES; PHARMACEUTICAL PREPARATIONS FOR THE PREVENTION AND TREATMENT OF DISORDERS AND DISEASES OF THE CENTRAL NERVOUS, PERIPHERAL NERVOUS AND RESPIRATORY SYSTEMS; PHARMACEUTICAL PREPARATIONS FOR THE PREVENTION AND TREATMENT OF SLEEP DISORDERS, IN CLASS 5 (U.S. CLS. 6, 18, 44, 46, 51 AND 52).

FIRST USE 1-6-2011; IN COMMERCE 1-6-2011.

THE MARK CONSISTS OF STANDARD CHARACTERS WITHOUT CLAIM TO ANY PARTICULAR FONT, STYLE, SIZE, OR COLOR.

PRIORITY CLAIMED UNDER SEC. 44(D) ON JAPAN APPLICATION NO. 2009-086298, FILED 11-13-2009.

SN 77-883,223, FILED 12-1-2009.

BRIAN NEVILLE, EXAMINING ATTORNEY

David J. Kappos

Director of the United States Patent and Trademark Office

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TRADEMARK ASSIGNMENT COVER SHEET

Electronic Version v1.1
Stylesheet Version v1.2

ETAS ID: TM310529

SUBMISSION TYPE:	NEW ASSIGNMENT
NATURE OF CONVEYANCE:	CHANGE OF NAME

CONVEYING PARTY DATA

Name	Formerly	Execution Date	Entity Type
Dainippon Sumitomo Pharma Co., Ltd.		06/19/2014	CORPORATION: JAPAN

RECEIVING PARTY DATA

Name:	Sumitomo Dainippon Pharma Co., Ltd.
Street Address:	6-8, Doshomachi 2-chome, Chuo-ku Osaka-shi
City:	Osaka
State/Country:	JAPAN
Entity Type:	CORPORATION: JAPAN

PROPERTY NUMBERS Total: 8

Property Type	Number	Word Mark
Serial Number:	86008711	DAINIPPON SUMITOMO PHARMA
Registration Number:	3221521	
Registration Number:	3727530	APTIOM
Registration Number:	3708035	LATUDA
Registration Number:	4096601	SUNOVION
Registration Number:	4440801	HEALTHY BODIES, HEALTHY LIVES
Registration Number:	4440802	SUNOVION HEALTHY BODIES, HEALTHY LIVES
Registration Number:	4289489	

OP $215.00 86008711

CORRESPONDENCE DATA

Fax Number: 2027218250

Correspondence will be sent to the e-mail address first; if that is unsuccessful, it will be sent using a fax number, if provided; if that is unsuccessful, it will be sent via US Mail.

Phone: 202-721-8200
Email: wlp@wenderoth.com
Correspondent Name: Christopher S. Adkins
Address Line 1: 1030 15th Street, N.W., Suite 400 East
Address Line 4: WASHINGTON, D.C. 20005

NAME OF SUBMITTER:	Christopher S. Adkins
SIGNATURE:	/Christopher S. Adkins/
DATE SIGNED:	07/14/2014

Total Attachments: 0

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